

➤ [Hearing Records ...](#)

** **07hr_CRule_07-090_SC-PHSILTCP_pt01**

**WISCONSIN STATE
LEGISLATURE ...
PUBLIC HEARING
COMMITTEE RECORDS**

2007-08

(session year)

Senate

(Assembly, Senate or Joint)

**Committee on
Public Health, Senior
Issues, Long Term
Care and Privacy**

(SC-PHSILTCP)

(FORM UPDATED: 07/02/2010)

COMMITTEE NOTICES ...

➤ [Committee Reports ... CR](#)
**

➤ [Executive Sessions ... ES](#)
**

➤ [Public Hearings ... PH](#)
**

➤ [Record of Comm. Proceedings ... RCP](#)
**

**INFORMATION COLLECTED BY
COMMITTEE FOR AND AGAINST
PROPOSAL ...**

➤ [Appointments ... Appt](#)
**

Name:

➤ [Clearinghouse Rules ... CRule](#)
**

➤ [Hearing Records ... HR](#) (bills and resolutions)
**

➤ [Miscellaneous ... Misc](#)
**

()



State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Kevin R. Hayden, Secretary

November 27, 2007

The Honorable Fred Risser, President
Wisconsin State Senate
State Capitol, Room 220 South
Madison, WI 53702

The Honorable Michael Huebsch, Speaker
Wisconsin State Assembly
State Capitol, Room 211 West
Madison, WI 53702

Re: Clearinghouse Rule 07-090
HFS 145, relating to student immunizations: disease list revisions and reporting.

Gentlemen:

In accordance with the provisions of s. 227.19 (2), Stats., you are hereby notified that the above-mentioned rules are in final draft form. This notice and the report required by s. 227.19 (3), Stats., are submitted herewith in triplicate.

The rules were submitted to the Legislative Council for review under s. 227.15, Stats. A copy of the Council's report is also enclosed.

If you have any questions about the rules, please contact Marjorie Hurie at 608-264-9892.

Sincerely,

Kevin R. Hayden
Secretary

cc Gary Poulson, Assistant Revisor of Statutes
Senator Robert Jauch, JCRAR
Representative Daniel LeMahieu, JCRAR
Marjorie Hurie, DHFS-DPH
Katie Plona, DHFS Secretary's Office

**ADMINISTRATIVE RULES
REPORT TO LEGISLATURE
CLEARINGHOUSE RULE 07-090**

By the Department of Health and Family Services relating to ch. HFS 145, Control of Communicable Diseases

Basis and Purpose of Proposed Rule

Statutory Authority:

- Section 227.11 (2), Stats., authorizes state agencies to promulgate rules that are necessary to operate their programs.
- Sections 252.02 (4) and (7), Stats., authorizes the Department to promulgate rules to prevent and control communicable diseases.
- Section 254.51 (3), Stats., authorizes the Department to promulgate rules that establish measures for prevention, surveillance and control of human disease that is associated with animal-borne and vector-borne disease transmission.
- Section 990.01 (5g), Stats., defines communicable disease as any disease that the Department determines by rule to be communicable in fact.

Purpose:

The Department is authorized by s. 990.01 (5g), Stats., to define communicable diseases by rule and by s. 252.02 (1), Stats., to establish surveillance systems for communicable diseases. The Department's surveillance system requires medical providers, health care facilities and laboratories to report the communicable diseases listed in ch. HFS 145 Appendix A to the local health officer or the state epidemiologist. At the national level, the Council of State and Territorial Epidemiologists (CSTE) recommends reportable diseases by adding them to the list of Nationally Notifiable Infectious Diseases (NNID). The diseases CSTE places under surveillance are typically novel pathogens or those with severe manifestations whose transmission is amenable to control by public health measures. States are encouraged to establish parallel reporting requirements. Accordingly, the Department proposes to add the following six NNID listed diseases to ch. HFS 145 Appendix A:

1. Influenza-associated pediatric deaths
2. Influenza A virus infection, novel subtypes
3. Poliovirus infection, nonparalytic
4. Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)
5. Vancomycin-intermediate *Staphylococcus aureus* (VISA) infections and Vancomycin-resistant *Staphylococcus aureus* (VRSA) infections
6. Vibriosis

Additionally, the Department proposes to add the following three diseases which are not on the NNID list to ch. HFS 145 Appendix A:

1. Any illness caused by an agent that is foreign, exotic or unusual to Wisconsin, and that has public health implications. Section 250.02, Stats., authorizes the Department to take action to ascertain the presence of any communicable disease. This generic reporting requirement is in lieu of a long listing of individual exotic diseases that are rare but have major public ramifications. It also takes into account the possible emergence of important diseases that are as yet unknown. Each state adjacent to Wisconsin requires that unusual illnesses be reported.
2. Lymphocytic Choriomeningitis Virus (LCMV) infections. In 2003, LCMV was transmitted in organs from an infected Wisconsin donor to four organ recipients. Implementation of public health measures upon identification of a case could potentially limit further exposures.
3. Transmissible spongiform encephalopathy (TSE, human). Approximately 50% of states currently mandate reporting of human TSEs and the Division of Public Health already maintains surveillance for human TSEs. Mandatory reporting will simplify the process of obtaining clinical information, especially from out-of-state

providers, and will permit the Department to describe more accurately the burden of endemic TSEs of humans.

Additionally, the Department proposes to delete eight diseases, none of which are on the NNID list, from ch. HFS 145 Appendix A. The Department does not anticipate that there will be any adverse impact on the public from deletion of the eight diseases from mandatory reporting:

1. Amebiasis
2. Cat scratch disease (infection caused by *Bartonella* species)
3. Encephalitis, viral (other than arboviral)
4. Genital herpes infection (first episode identified by health care provider)
5. Hepatitis non-A, non-B, (acute)
6. Meningitis, viral (other than arboviral)
7. Reye syndrome
8. Typhus fever

Additionally, the Department proposes to change the way the following five diseases are listed in ch. HFS 145 Appendix A:

1. Change Arboviral infection (encephalitis/meningitis) to Arboviral Disease. The proposed change in terminology makes reporting requirements consistent with current Wisconsin public health practice. This group of diseases is currently on the NNID list.
2. Change *E. coli* 0157:H7, and other enterohemorrhagic *E. coli*, enteropathogenic *E. coli*, enteroinvasive *E. coli*, enterotoxigenic *E. coli* to *E. coli* 0157:H7 and other Shiga toxin-producing *E. coli* (STEC), enteropathogenic *E. coli*, enteroinvasive *E. coli*, and enterotoxigenic *E. coli*. In 2005, CSTE recommended that the enterohemorrhagic *Escherichia coli* (EHEC) condition name be revised to Shiga toxin-producing *Escherichia coli* (STEC) to more accurately describe the condition under surveillance.
3. Change Hepatitis E from a category I disease to a category II disease because this disease does not occur often in the United States and person-to-person transmission is uncommon.
4. Change Suspected Outbreaks of Other Acute or Occupational-related diseases from category II to category I because a possible outbreak requires immediate attention.
5. Change Varicella (chickenpox) – report by number of cases only to Varicella (chickenpox). In 2003, CDC encouraged all states to establish individual case reporting systems to monitor the impact of the varicella vaccination program on varicella morbidity. This level of surveillance is now operationally feasible because the number of cases is far fewer than in the pre-vaccination era. Varicella is on the NNID list.

Lastly, the Department proposes to:

1. Alphabetize the diseases in ch. HFS 145 Appendix A to make the list easier for persons reporting communicable diseases to use.
2. Allow reports of communicable diseases to be submitted electronically. Electronic transmission of reports currently occurs and is expected to increase.
3. Cite the most recent editions of the *Sexually Transmitted Diseases Treatment Guidelines* and the *Control of Communicable Diseases Manual* to make the references current.
4. Require laboratories to forward specimens to the State Laboratory of Hygiene for confirmatory or investigation purposes if requested by the State Epidemiologist.
5. Require laboratories and health care facilities to report a negative test result on a case or a suspected case to justify release from isolation or quarantine if requested by the State Epidemiologist or Local Health Officer.
6. Remove language requiring a person, laboratory or health care facility to report the total number of cases of other communicable diseases listed in ch. HFS 145 Appendix A to the local health officer on a weekly basis because varicella, the only disease reported in this manner, will now be reported as individual cases.

The intended goals of the proposed rulemaking are to make communicable disease reporting requirements in Wisconsin current, consistent with CSTE recommendations and supportive of Wisconsin public health practice.

Responses to Legislative Council Rules Clearinghouse Recommendations

The Department accepted the comments made by the Legislative Council Rules Clearinghouse and modified the proposed rule where suggested.

Final Regulatory Flexibility Analysis

This rulemaking is unlikely to have a significant economic impact on the private sector generally, and any health care facilities or laboratories that may meet the definition of small business in 227.114 (1), Stats., in particular. It includes no fees, failure to comply with the rulemaking carries no penalties and communicable disease reporting mechanisms are already in place. Usual costs to the private sector include completing and mailing communicable disease case report forms, or keying-in and transmitting data electronically, to local health departments or the Department. These tasks are frequently performed by the infection control practitioner or clerical staff. Since the largest laboratories will be reporting automatically through electronic laboratory reporting, there will be minimal impact on these laboratories. Requests from the State Epidemiologist or the Local Health Officer for negative test results to justify release from isolation or quarantine are anticipated to be infrequent, as are requests from the State Epidemiologist that specimens to be forwarded to a public health laboratory for confirmatory or investigation purposes.

Changes to the Analysis or Fiscal Estimate

Analysis

No changes were made to the rule's fiscal analysis.

Fiscal Estimate

No changes were made to the fiscal estimate.

Public Hearing Summary

Public hearings were held in Madison on November 12, 2007 and in Wausau on November 13, 2007. There were no attendees. No comments were received during the comment period. The development phase of the proposed rules included circulation of a draft to the Wisconsin Council of Immunization Practices, Local Health Officers, the Wisconsin Association of Local Health Departments and Boards, the Wisconsin Chapter of the Association of Practitioners in Infection Control, the State Laboratory of Hygiene and its Laboratory Reporting Network, and the Bioterrorism Surveillance Epidemiology Workgroup. The draft was revised in response to comments received during the rule development phase.





WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Ronald Sklansky
Clearinghouse Director

Richard Sweet
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Laura D. Rose
Legislative Council Deputy Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **07-090**

AN ORDER to repeal HFS 145.04 (3) (c); to amend HFS 145.03 (19) and Note and (20), 145.04 (2) (b), 145.05 (2), (3) and Note, 145.10 (1) and Note, and 145.22 and Note; to repeal and recreate HFS 145 Appendix A; and to create HFS 145.04 (1) (bg), (br), and (cm), relating to communicable diseases, and affecting small businesses.

Submitted by **DEPARTMENT OF HEALTH AND FAMILY SERVICES**

10-11-2007 RECEIVED BY LEGISLATIVE COUNCIL.

11-01-2007 REPORT SENT TO AGENCY.

RNS:LR

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]
Comment Attached YES NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]
Comment Attached YES NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]
Comment Attached YES NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS
[s. 227.15 (2) (e)]
Comment Attached YES NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]
Comment Attached YES NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL
REGULATIONS [s. 227.15 (2) (g)]
Comment Attached YES NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]
Comment Attached YES NO



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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Clearinghouse Director

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Laura D. Rose
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CLEARINGHOUSE RULE 07-090

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated January 2005.]

2. Form, Style and Placement in Administrative Code

- a. In the citations to statutory authority, the reference to s. 900.01 (5g) should be to s. 990.01 (5g).
- b. In s. HFS 145.03 (19) “edited by” should not be stricken through.
- c. In the note to s. HFS 145.03 (19), the reference to the Revisor of Statutes Bureau should be changed to the Legislative Reference Bureau (LRB); the 2007-09 Biennial Budget Act transfers the duties of the Revisor to the LRB.

5. Clarity, Grammar, Punctuation and Use of Plain Language

- a. In s. HFS 145.04 (2) (b), a comma should be inserted after the word “verbal.”
- b. In s. HFS 145.05 (3) and (4), the name “David” is misspelled.

**PROPOSED ORDER OF
DEPARTMENT OF HEALTH AND FAMILY SERVICES
TO ADOPT RULES**

The Wisconsin Department of Health and Family Services proposes to **repeal** HFS 145.04 (3) (c); **to amend** HFS 145.03 (19) and Note, and (20), 145.04 (2) (b), 145.05 (2), (3) and Note, 145.10 (1) and Note, 145.22 and Note; **to repeal and recreate** HFS 145 APPENDIX A; and **to create** HFS 145.04 (1) (bg), (br) and (cm) rules relating to communicable diseases, and affecting small businesses.

SUMMARY OF PROPOSED RULE

Statute interpreted: Chapter 252 and ss. 254.04 and 254.51, Stats.

990.01(5g)

Statutory authority: Sections 227.11, 252.02 (4) and (7), 254.51 (3), and ~~900.01~~ (5g), Stats.

Explanation of agency authority:

Section 227.11 (2), Stats., authorizes state agencies to promulgate rules that are necessary to operate their programs, s. 252.02 (4) and (7), Stats., authorizes the Department to promulgate rules to prevent and control communicable diseases, s. 254.51 (3), Stats., authorizes the Department to promulgate rules that establish measures for prevention, surveillance and control of human disease that is associated with animal-borne and vector-borne disease transmission, and s. 990.01 (5g), Stats., defines communicable disease as any disease that the Department determines by rule to be communicable in fact.

Related statute or rule: See subsections on statutes interpreted and statutory authority.

Plain language analysis:

The Department is authorized by s. 990.01 (5g), Stats., to define communicable diseases by rule and by s. 252.02 (1), Stats., to establish surveillance systems for communicable diseases. The Department's surveillance system requires medical providers, health care facilities and laboratories to report the communicable diseases listed in ch. HFS 145 Appendix A to the local health officer or the state epidemiologist. At the national level, the Council of State and Territorial Epidemiologists (CSTE) recommends reportable diseases by adding them to the list of Nationally Notifiable Infectious Diseases (NNID). The diseases CSTE places under surveillance are typically novel pathogens or those with severe manifestations whose transmission is amenable to control by public health measures. States are encouraged to establish parallel reporting requirements. Accordingly, the Department proposes to add the following six NNID listed diseases to ch. HFS 145 Appendix A:

1. Influenza-associated pediatric deaths

2. Influenza A virus infection, novel subtypes
3. Poliovirus infection, nonparalytic
4. Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)
5. Vancomycin-intermediate *Staphylococcus aureus* (VISA) infections and Vancomycin-resistant *Staphylococcus aureus* (VRSA) infections
6. Vibriosis

Additionally, the Department proposes to add the following three diseases which are not on the NNID list to ch. HFS 145 Appendix A:

1. Any illness caused by an agent that is foreign, exotic or unusual to Wisconsin, and that has public health implications. Section 250.02, Stats., authorizes the Department to take action to ascertain the presence of any communicable disease. This generic reporting requirement is in lieu of a long listing of individual exotic diseases that are rare but have major public ramifications. It also takes into account the possible emergence of important diseases that are as yet unknown. Each state adjacent to Wisconsin requires that unusual illnesses be reported.
2. Lymphocytic Choriomeningitis Virus (LCMV) infections. In 2003, LCMV was transmitted in organs from an infected Wisconsin donor to four organ recipients. Implementation of public health measures upon identification of a case could potentially limit further exposures.
3. Transmissible spongiform encephalitis (TSE, human). Approximately 50% of states currently mandate reporting of human TSEs and the Division of Public Health already maintains surveillance for human TSEs. Mandatory reporting will simplify the process of obtaining clinical information, especially from out-of-state providers, and will permit the Department to describe more accurately the burden of endemic TSEs of humans.

Additionally, the Department proposes to delete eight diseases, none of which are on the NNID list, from ch. HFS 145 Appendix A. The Department does not anticipate that there will be any adverse impact on the public from deletion of the eight diseases from mandatory reporting:

1. Amebiasis
2. Cat scratch disease (infection caused by *Bartonella* species)
3. Encephalitis, viral (other than arboviral)
4. Genital herpes infection (first episode identified by health care provider)
5. Hepatitis non-A, non-B, (acute)
6. Meningitis, viral (other than arboviral)
7. Reye syndrome
8. Typhus fever

Additionally, the Department proposes to change the way the following five diseases are listed in ch. HFS 145 Appendix A:

1. Change Arboviral infection (encephalitis/meningitis) to Arboviral Disease. The proposed change in terminology makes reporting requirements consistent with current Wisconsin public health practice. This group of diseases is currently on the NNID list.

2. Change *E. coli* 0157:H7, and other enterohemorrhagic *E. coli*, enteropathogenic *E. coli*, enteroinvasive *E. coli*, enterotoxigenic *E. coli* to *E. coli* 0157:H7 and other Shiga toxin-producing *E. coli* (STEC), enteropathogenic *E. coli*, enteroinvasive *E. coli*, and enterotoxigenic *E. coli*. In 2005, CSTE recommended that the enterohemorrhagic *Escherichia coli* (EHEC) condition name be revised to Shiga toxin-producing *Escherichia coli* (STEC) to more accurately describe the condition under surveillance.
3. Change Hepatitis E from a category I disease to a category II disease because this disease does not occur often in the United States and person-to-person transmission is uncommon.
4. Change Suspected Outbreaks of Other Acute or Occupational-related diseases from category II to category I because a possible outbreak requires immediate attention.
5. Change Varicella (chickenpox) – report by number of cases only to Varicella (chickenpox). In 2003, CDC encouraged all states to establish individual case reporting systems to monitor the impact of the varicella vaccination program on varicella morbidity. This level of surveillance is now operationally feasible because the number of cases is far fewer than in the pre-vaccination era. Varicella is on the NNID list.

Lastly, the Department proposes to:

- 1) Alphabetize the diseases in ch. HFS 145 Appendix A to make the list easier for persons reporting communicable diseases to use.
- 2) Allow reports of communicable diseases to be submitted electronically. Electronic transmission of reports currently occurs and is expected to increase.
- 3) Cite the most recent editions of the *Sexually Transmitted Diseases Treatment Guidelines* and the *Control of Communicable Diseases Manual* to make the references current.
- 4) Require laboratories to forward specimens to the State Laboratory of Hygiene for confirmatory or investigation purposes if requested by the State Epidemiologist.
- 5) Require laboratories and health care facilities to report a negative test result on a case or a suspected case to justify release from isolation or quarantine if requested by the State Epidemiologist or Local Health Officer.
- 6) Remove language requiring a person, laboratory or health care facility to report the total number of cases of other communicable diseases listed in ch. HFS 145 Appendix A to the local health officer on a weekly basis because varicella, the only disease reported in this manner, will now be reported as individual cases.

The intended goals of the proposed rulemaking are to make communicable disease reporting requirements in Wisconsin current, consistent with CSTE recommendations and supportive of Wisconsin public health practice. Instead of regulatory action, medical providers, health care facilities and laboratories could be asked to submit reports voluntarily. However, such reporting would be incomplete and more staff time would be required to solicit the reports. Without this proposed rulemaking, disease reporters would continue to complete and submit reports of some communicable diseases unnecessarily, national communicable disease data would not reflect diseases occurring in Wisconsin, and the rule language would be outdated.

Members of the public who may be affected by the proposed rulemaking are those who acquire one of the communicable diseases the proposed rulemaking adds. Other members of the public who may be affected are the individual's family members or other contacts who were spared infection because public health measures were applied.

Summary of, and comparison with, existing or proposed federal regulations:

There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

Comparison with rules in adjacent states:

Illinois:

Illinois Administrative Code Title 77, Chapter 1, Subchapter K, Part 690, Section 690 requires reporting any unusual case or cluster of cases that may indicate a public health hazard (690.295), VISA/VRSA (690.661), and varicella (690.350). These rules became effective 6/30/03 and are currently being updated. The new rules will require reporting of influenza-associated pediatric death, SARS, TSE (as Creutzfeldt Jakob Disease) and vibriosis. These rules have been sent out for comment and are expected to take effect in the fall of 2007.

Iowa:

Iowa Administrative Code (IAC) 641-1.3 (139A) makes reportable a number of diseases and conditions, including any uncommon disease and vancomycin-resistant *Staphylococcus aureus*. IAC 641-1.1 (139A) includes SARS in the definition of quarantinable diseases. Quarantinable diseases are immediately reportable under 641-1.4 (1). Isolates of organisms from diseases on the list of reportable diseases or conditions marked with a "~" must be sent to the University of Iowa Hygienic Laboratory. IAC 641-1.4 (3) requires the reporting agency to provide test results necessary to the investigation, including positive, pending and negative test results. These rules became effective 3/10/04.

Michigan:

Michigan Administrative Code 325.172 makes reportable a number of diseases and conditions, including the unusual occurrence, outbreak or epidemic of any condition (bbbb), laboratory-confirmed poliovirus infection (vv), SARS (jjj), TSE [as spongiform encephalopathy (lll)], VISA/VRSA (mmm), and chickenpox (l). These rules became effective 9/23/05.

Minnesota:

Minnesota Chapter 4605.7040 makes reportable cases, suspected cases, carriers and deaths due to a number of diseases including influenza (26), SARS (15), TSE (52, VISA/VRSA (46), *Vibrio* species (58), and chickenpox [56 (a)]. Ch. 4605.7050 requires reporting of any unusual case incidence. Ch. 4605.7030 Subpart 3 B requires laboratories to forward to the Minnesota Department of Health Public Health Laboratory all clinical materials specified in the chapter or upon the request of the commissioner. These rules became effective 9/13/05.

The tables below compare the important elements in the Department's proposed rulemaking with current and proposed communicable disease reporting rules in Illinois, Iowa, Michigan and Minnesota.

State	Any unusual illness	Influenza-associated pediatric death	LCMV	Poliovirus, nonparalytic	SARS-CoV	TSE	VISA & VRSA	Vibriosis
Illinois	Yes	No, but soon	No	No	No, but soon	No, but soon	Yes - Both	No, but soon
Iowa	Yes	No	No	No	Yes	No	Yes - VRSA	No
Michigan	Yes	No	No	Yes	Yes	Yes	Yes - Both	No
Minnesota	Yes	Yes	No	No	Yes	Yes	Yes - Both	Yes

State	Individual Varicella Case Reports	Laboratory must forward specimen upon request	Laboratory must report negative test result upon request
Illinois	Yes	Yes	No
Iowa	No	Yes	Yes
Michigan	Yes	No	No
Minnesota	Yes	Yes	No

Summary: All of Wisconsin's neighboring states require the reporting of illnesses caused by unusual agents. The reporting requirements this rulemaking proposes are most similar to those in Minnesota, the state with the most recently enacted reporting requirements. The reporting requirements in Illinois will also closely resemble those Wisconsin proposes when its proposed rules take effect later in 2007. However, none of Wisconsin's neighboring states require that LCMV be specifically reported. LCMV cases in those states would still be reported under the requirement that illnesses caused by unusual agents be reported.

Summary of factual data and analytical methodologies:

This rule was amended in consultation with Bureau of Communicable Diseases and Preparedness Communicable Disease Epidemiology Section staff. Wisconsin's list of reportable diseases in ch. 145 Appendix A was reviewed and compared to the CSTE NNID list in the 2007 Summary of Changes to the Nationally Notifiable Diseases Surveillance System that the Centers for Disease Control and Prevention sent to State and Territorial Epidemiologists on December 5, 2006. Additionally, the communicable disease reporting requirements in states adjacent to Wisconsin were identified and described. A draft of the amended rule was circulated to and revised in response to comments from the following groups: the Wisconsin Association of Local Health Departments and Boards; Local Health Officers; the State Laboratory of Hygiene and its Laboratory Reporting Network; the Association for Professionals in Infection Control; the Wisconsin Council on Immunization Practices and the Surveillance Epidemiology Workgroup.

Analysis and supporting documents used to determine effect on small business:

Chapter HFS 145 requires medical providers, health care facilities and laboratories to report communicable diseases listed in Appendix A to the Local Health Officer or the State Epidemiologist. This rulemaking proposes adding 9 diseases to, and subtracting 8 diseases from, ch. HFS 145 Appendix A. The rulemaking includes no fees and failure to comply with the

rulemaking carries no penalties. Costs to the private sector include completing and mailing communicable disease case report forms, or keying-in and transmitting data electronically, to local health departments or the Department. Communicable disease reporting is frequently performed by the infection control practitioner or clerical staff.

This rulemaking is unlikely to have a significant economic impact on the private sector generally, and small businesses in particular, for the following reasons:

- Communicable disease reporting requirements and reporting mechanisms have been in place for many years.
- Additions of reportable diseases to ch. HFS 145 Appendix A have been balanced by deletions from it. Some of the deleted diseases which occur relatively frequently, e.g., genital herpes and cat scratch fever, will no longer be reported.
- Most of the diseases being added to the list, although serious in nature and of public health importance, occur so rarely that few if any cases are expected annually.
- Since the largest laboratories performing testing will be reporting automatically through electronic laboratory reporting, there will be minimal impact on these laboratories.

Effect on small business:

Pursuant to the foregoing analysis, the Department believes that these rules will not have a significant economic impact on the health care facilities or laboratories that meet the definition of small businesses.

Agency contact person:

Marjorie Hurie, RN, MS
Bureau of Communicable Diseases
PO Box 2659
Madison, WI 53701
608-264-9892

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at <http://adminrules.wisconsin.gov> after the hearing is scheduled.

TEXT OF PROPOSED RULE

Section 1: HFS 145.03 (19) and Note, and (20) are amended to read:

HFS 145.03 (19) "Other disease or condition having the potential to affect the health of other persons" means a disease that can be transmitted from one person to another but that is not listed in Appendix A of this chapter and therefore is not reportable under this chapter, although it is listed in *Control of Communicable Diseases Manual*, ~~16th edition (1995)~~ 18th edition (2004), edited by ~~Abram S. Benenson~~ David L. Heymann, and published by the American Public Health Association, unless specified otherwise by the state epidemiologist.

Note: The handbook, *Control of Communicable Diseases Manual*, ~~16th edition (1995)~~ 18th edition (2004), edited by ~~Abram S. Benenson~~ David L. Heymann, is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau, and is available for purchase from the American Public Health Association, ~~1015 Fifteenth St., NW, Washington, D.C., 20005~~ Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

(20) "Outbreak" means ~~the occurrence of communicable disease cases, in a particular geographical area of the state, in excess of the expected number of cases~~ an unusual aggregation of health events that are grouped together in a short time period and limited geographic area.

Section 2. HFS 145.04 (1) (bg), (br) and (cm) are created to read:

HFS 145.04 (1) (bg) Each laboratory shall forward a specimen to the state laboratory of hygiene, or another laboratory designated by the state epidemiologist, for confirmatory or investigation purposes if requested by the state epidemiologist.

(br) Each laboratory shall report a negative test result to the local health officer to justify release from isolation or quarantine if requested by the state epidemiologist or the local health officer.

(cm) Each health care facility shall report a negative test result to the local health officer to justify release from isolation or quarantine if requested by the state epidemiologist or the local health officer.

Section 3. HFS 145.04 (2) (b) is amended to read:

HFS 145.04 (2) (b) Reports may be written, ~~or verbal~~ or by electronic transmission. Written reports shall be on the individual case report form provided by the department and distributed by the local health officer or on a form containing the information required under par. (a). Reports shall be submitted to the local health officer or, if required under Appendix A of this chapter, to the state epidemiologist.

Section 4. HFS 145.04 (3) (c) is repealed.

Section 5. HFS 145.05 (2), (3) and (4) Note are amended to read:

HFS 145.05 (2) Local health officers shall follow the methods of control set out in section 9 under each communicable disease listed in the ~~17th~~ 18th edition (2004) of *Control of Communicable Diseases Manual*, edited by ~~James Chin~~ David L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist. Specific medical treatment shall be prescribed by a physician or an advanced practice nurse prescriber.

(3) Any person licensed under ch. 441 or 448, Stats., attending a person with a communicable disease shall instruct the person in the applicable methods of control contained in Control of Communicable Diseases Manual, 17th18th edition (2000)(2004), edited by ~~James Chin~~David L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist, and shall cooperate with the local health officer and the department in their investigation and control procedures.

(4) Note: The handbook, Control of Communicable Diseases Manual, 17th18th edition 2000(2004), edited by ~~James Chin~~David L. Heymann, is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau, and is available for purchase from the American Public Health Association, 1015 Fifteenth St., NW, Washington, DC 20005 Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

Section 6. HFS 145.10 (1) and Note are amended to read:

HFS 145.10 Restriction and management of patients and contacts. (1) All persons with infectious tuberculosis or suspected tuberculosis, and their contacts, shall exercise all reasonable precautions to prevent the infection of others, under the methods of control set out in section 9 under tuberculosis, pages ~~525565~~ to ~~530572~~, listed in the 17th18th edition (2000)(2004) of Control of Communicable Diseases Manual, edited by ~~James Chin~~David L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist.

Note: The handbook Control of Communicable Diseases Manual, 17th18th edition (2000)(2004), edited by ~~James Chin~~David L. Heymann, is on file in the Revisor of Statutes Bureau and the Secretary of State's Office, and is available for purchase from the American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710 Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

Section 7. HFS 145.22 and Note are amended to read:

HFS 145.22 Treatment guidelines. Nationally recognized guidelines, including the "1998 Guidelines for Treatment of Sexually Transmitted Diseases" "Sexually Transmitted Diseases Treatment Guidelines, 2006" published by the U.S. Department of Health and Human Services, shall be considered in the treatment of sexually transmitted diseases unless otherwise specified by the state epidemiologist. Specific medical treatment shall be prescribed by a physician or advanced practice nurse prescriber.

Note: The publication, "1998 Guidelines for Treatment of Sexually Transmitted Diseases" "Sexually Transmitted Diseases Treatment Guidelines, 2006" is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State's Office, and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402-9325. Telephone: (202) 512-1800.

Section 8. HFS 145 APPENDIX A is repealed and recreated to read:

CHAPTER HFS 145

APPENDIX A

COMMUNICABLE DISEASES AND OTHER NOTIFIABLE CONDITIONS

CATEGORY I:

The following diseases are of urgent public health importance and shall be reported IMMEDIATELY by telephone or fax to the patient's local health officer upon identification of a case or suspected case. In addition to the immediate report, complete and mail an Acute and Communicable Diseases Case Report (DOH 4151) to the address on the form, or enter the data into the Wisconsin Electronic Disease Surveillance System, within 24 hours. Public health intervention is expected as indicated. See s. HFS 145.04 (3) (a).

Any illness caused by an agent that is foreign, exotic or unusual to Wisconsin, and that has public health implications⁴

Anthrax^{1,4,5}

Botulism^{1,4}

Botulism, infant^{1,2,4}

Cholera^{1,3,4}

Diphtheria^{1,3,4,5}

Haemophilus influenzae invasive disease, (including epiglottitis)^{1,2,3,5}

Hantavirus infection^{1,2,4,5}

Hepatitis A^{1,2,3,4,5}

Measles^{1,2,3,4,5}

Meningococcal disease^{1,2,3,4,5}

Outbreaks, foodborne or waterborne^{1,2,3,4}

Outbreaks, suspected, of other acute or occupationally-related diseases

Pertussis (whooping cough)^{1,2,3,4,5}

Plague^{1,4,5}

Poliovirus infection (paralytic or nonparalytic)^{1,4,5}

Rabies (human)^{1,4,5}

Ricin toxin^{4,5}

Rubella^{1,2,4,5}

Rubella (congenital syndrome)^{1,2,5}

Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)^{1,2,3,4}

Smallpox^{4,5}

Tuberculosis^{1,2,3,4,5}

Vancomycin-intermediate Staphylococcus aureus (VISA) and Vancomycin-resistant Staphylococcus aureus (VRSA) infection^{1,4,5}

Yellow fever^{1,4}

CATEGORY II:

The following diseases shall be reported to the local health officer on an Acute and Communicable Disease Case Report (DOH 4151) or by other means or by entering the data into the Wisconsin Electronic Disease Surveillance System within 72 hours of the identification of a case or suspected case. See s. HFS 145.04 (3) (b).

Arboviral disease^{1,2,4}

Babesiosis^{4,5}

Blastomycosis⁵

Brucellosis^{1,4}

Campylobacteriosis (campylobacter infection)^{3,4}

Chancroid^{1,2}

Chlamydia trachomatis infection^{2,4,5}

Cryptosporidiosis^{1,2,3,4}

Cyclosporiasis^{1,4,5}

Ehrlichiosis (anaplasmosis)^{1,5}

E. coli 0157:H7, other Shiga toxin-producing E. coli (STEC), enteropathogenic E. coli, enteroinvasive E. coli, and enterotoxigenic E.

Meningitis, bacterial (other than Haemophilus influenzae, meningococcal or streptococcal, which are reportable as distinct diseases)²

Mumps^{1,2,4,5}

Mycobacterial disease (nontuberculous)

Psittacosis^{1,2,4}

Pelvic inflammatory disease²

Q Fever^{4,5}

Rheumatic fever (newly diagnosed and meeting the Jones criteria)⁵

Rocky Mountain spotted fever^{1,2,4,5}

Salmonellosis^{1,3,4}

Syphilis^{1,2,4,5}

coli.^{1,2,3,4}
Giardiasis^{3,4}
Gonorrhea^{1,2,4,5}
Hemolytic uremic syndrome^{1,2,4}
Hepatitis B^{1,2,3,4,5}
Hepatitis C^{1,2}
Hepatitis D^{2,3,4,5}
Hepatitis E^{3,4}
Histoplasmosis⁵
Influenza-associated pediatric death¹
Influenza A virus infection, novel subtypes
Kawasaki disease²
Legionellosis^{1,2,4}
Leprosy (Hansen Disease)^{1,2,3,4,5}
Leptospirosis⁴
Listeriosis^{2,4}
Lyme disease^{1,2}
Lymphocytic Choriomeningitis Virus (LCMV) infection⁴
Malaria^{1,2,4}

Shigellosis^{1,3,4}
Streptococcal disease (all invasive disease caused by Groups A and B Streptococci)
Streptococcus pneumoniae invasive disease (invasive pneumococcal)¹
Tetanus^{1,2,5}
Toxic shock syndrome^{1,2}
Toxic substance related diseases:
 Infant methemoglobinemia
 Lead intoxication (specify Pb levels)
 Other metal and pesticide poisonings
Toxoplasmosis
Transmissible spongiform encephalitis (TSE, human)
Trichinosis^{1,2,4}
Tularemia⁴
Typhoid fever^{1,2,3,4}
Varicella (chickenpox)^{1,3,5}
Vibriosis^{1,3,4}
Yersiniosis^{3,4}

CATEGORY III:

The following diseases shall be reported to the state epidemiologist on an AIDS Case Report (DOH 4264) or a Wisconsin Human Immunodeficiency Virus (HIV) Infection Confidential Case Report (DOH 4338) or by other means within 72 hours after identification of a case or suspected case. See s. 252.15 (7) (b), Stats., and s. HFS 145.04 (3) (b).

Acquired Immune Deficiency Syndrome (AIDS)^{1,2,4}
Human immunodeficiency virus (HIV) infection^{2,4}
CD4 + T-lymphocyte count < 200/mL, or CD4 + T-lymphocyte percentage of total lymphocytes of < 14²

Key:

¹Infectious diseases designated as notifiable at the national level.

²Wisconsin or CDC follow-up form is required. Local health departments have templates of these forms in the Epinet manual.

³High-risk assessment by local health department is needed to determine if patient or member of patient's household is employed in food handling, day care or health care.

⁴Source investigation by local health department is needed.

⁵Immediate treatment is recommended, i.e., antibiotic or biologic for the patient or contact or both.

EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health and Family Services

Dated:

Kevin R. Hayden, Department Secretary

SEAL:

ADMINISTRATIVE RULES – FISCAL ESTIMATE

1. Fiscal Estimate Version

Original Updated Corrected

2. Administrative Rule Chapter Title and Number

HFS 145, Control of Communicable Diseases

3. Subject

To revise ch. HFS 145, relating to communicable disease reporting and follow-up.

4. State Fiscal Effect:

<input checked="" type="checkbox"/> No Fiscal Effect	<input type="checkbox"/> Increase Existing Revenues	<input type="checkbox"/> Increase Costs
<input type="checkbox"/> Indeterminate	<input type="checkbox"/> Decrease Existing Revenues	<input type="checkbox"/> Yes <input type="checkbox"/> No May be possible to absorb within agency's budget.
		<input type="checkbox"/> Decrease Costs

5. Fund Sources Affected:

GPR FED PRO PRS SEG SEG-S

6. Affected Ch. 20, Stats. Appropriations:

7. Local Government Fiscal Effect:

<input checked="" type="checkbox"/> No Fiscal Effect	<input type="checkbox"/> Increase Revenues	<input type="checkbox"/> Increase Costs
<input type="checkbox"/> Indeterminate	<input type="checkbox"/> Decrease Revenues	<input type="checkbox"/> Decrease Costs

8. Local Government Units Affected:

Towns Villages Cities Counties School Districts WTCS Districts Others:

9. Private Sector Fiscal Effect (small businesses only):

<input checked="" type="checkbox"/> No Fiscal Effect	<input type="checkbox"/> Increase Revenues	<input type="checkbox"/> Increase Costs
<input type="checkbox"/> Indeterminate	<input type="checkbox"/> Decrease Revenues	<input type="checkbox"/> Yes <input type="checkbox"/> No May have significant economic impact on a substantial number of small businesses
	<input type="checkbox"/> Yes <input type="checkbox"/> No May have significant economic impact on a substantial number of small businesses	<input type="checkbox"/> Decrease Costs

10. Types of Small Businesses Affected:

Medical providers, health care facilities and laboratories

11. Fiscal Analysis Summary

These are updating amendments to the Department's rules for reporting communicable diseases and taking action to control their spread.

The rulemaking order adds 9 diseases to, deletes 8 diseases from, and changes the way 5 diseases appear on the list of reportable communicable diseases in Appendix A of the rules. The Department is authorized by s. 990.01 (5g), Stats., to add diseases to that list by rule. The rulemaking order also updates references, deletes outdated language, requires laboratories to forward specimens to a public health laboratory for additional testing if requested by the State Epidemiologist and requires laboratories and health care facilities to report negative test results to the local health officer if requested by the State Epidemiologist or the local health officer.

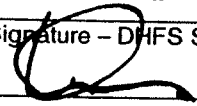
Anticipated costs to the Department include layout and printing costs associated with revising and reprinting the Division of Public Health's Communicable Disease Case Report form (DPH 4151); staff time to inform the mandated reporting agencies of the rule revisions through educational forums, e.g., Communicable Disease Spring Seminars, and scheduled meetings, e.g., regional Association of Practitioners of Infection Control chapter meetings and the State Laboratory of Hygiene's Laboratory Reporting Network; and staff time to prepare notices of the rule revisions for publication in the Wisconsin State Medical Journal, on the Department's web site and the Health Alert Network. These costs are insignificant and will be absorbed within the Bureau of Communicable Diseases and Preparedness budget and staff responsibilities.

The rule changes will not affect the expenditures or revenues of Local Health Departments. Local Health Officers are responsible under s. 252.03 (1), Stats., for investigating, preventing and controlling communicable diseases. Most of the diseases being added to Appendix A have been balanced by deletions from it and, with the exception of varicella (chickenpox), occur so rarely that few if any cases are expected annually. The addition of varicella reporting by individual case report to Appendix A (summary data on approximately 1,000 cases were reported in 2006) has been more than balanced by the deletion of genital herpes (more than 3,000 cases were reported in 2005).

This rulemaking is unlikely to have a significant economic impact on the private sector generally, and any health care facilities or laboratories that may meet the definition of small business in 227.114 (1), Stats., in particular. It includes no fees, failure to comply with the rulemaking carries no penalties and communicable disease reporting mechanisms are already in place. Usual costs to the private sector include completing and mailing communicable disease case reports forms, or keying-in and transmitting data electronically, to local health departments or the Department. These tasks are frequently performed by the infection control practitioner or clerical staff. Since the largest laboratories will be reporting automatically through electronic laboratory reporting, there will be minimal impact on these laboratories. Requests from the State Epidemiologist or the Local Health Officer for negative test results to justify release from isolation or quarantine are anticipated to be infrequent, as are requests from the State Epidemiologist that specimens to be forwarded to a public health laboratory for confirmatory or investigation purposes.

12. Long-Range Fiscal Implications

None known.

13. Name - Prepared by Marjorie Hurie	Telephone Number 608-264-9892	Date 7/18/07
14. Name - OSF Analyst Reviewer Ellen Hadidian	Telephone Number 608-266-8155	Date 9/28/07
Signature - DHFS Secretary or Designee 	Telephone Number 266-4452	Date 10-5-07



**PROPOSED ORDER OF
DEPARTMENT OF HEALTH AND FAMILY SERVICES
TO ADOPT RULES**

The Wisconsin Department of Health and Family Services proposes **to repeal** HFS 145.04 (3) (c); **to amend** HFS 145.03 (19) and Note, and (20), 145.04 (2) (b), 145.05 (2), (3) and Note, 145.10 (1) and Note, 145.22 and Note; **to repeal and recreate** HFS 145 APPENDIX A; and **to create** HFS 145.04 (1) (bg), (br) and (cm) rules relating to communicable diseases, and affecting small businesses.

SUMMARY OF PROPOSED RULE

Statute interpreted: Chapter 252 and ss. 254.04 and 254.51, Stats.

Statutory authority: Sections 227.11, 252.02 (4) and (7), 254.51 (3), and 990.01 (5g), Stats.

Explanation of agency authority:

Section 227.11 (2), Stats., authorizes state agencies to promulgate rules that are necessary to operate their programs, s. 252.02 (4) and (7), Stats., authorizes the Department to promulgate rules to prevent and control communicable diseases, s. 254.51 (3), Stats., authorizes the Department to promulgate rules that establish measures for prevention, surveillance and control of human disease that is associated with animal-borne and vector-borne disease transmission, and s. 990.01 (5g), Stats., defines communicable disease as any disease that the Department determines by rule to be communicable in fact.

Related statute or rule: See subsections on statutes interpreted and statutory authority.

Plain language analysis:

The Department is authorized by s. 990.01 (5g), Stats., to define communicable diseases by rule and by s. 252.02 (1), Stats., to establish surveillance systems for communicable diseases. The Department's surveillance system requires medical providers, health care facilities and laboratories to report the communicable diseases listed in ch. HFS 145 Appendix A to the local health officer or the state epidemiologist. At the national level, the Council of State and Territorial Epidemiologists (CSTE) recommends reportable diseases by adding them to the list of Nationally Notifiable Infectious Diseases (NNID). The diseases CSTE places under surveillance are typically novel pathogens or those with severe manifestations whose transmission is amenable to control by public health measures. States are encouraged to establish parallel reporting requirements. Accordingly, the Department proposes to add the following six NNID listed diseases to ch. HFS 145 Appendix A:

1. Influenza-associated pediatric deaths
2. Influenza A virus infection, novel subtypes

3. Poliovirus infection, nonparalytic
4. Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)
5. Vancomycin-intermediate *Staphylococcus aureus* (VISA) infections and Vancomycin-resistant *Staphylococcus aureus* (VRSA) infections
6. Vibriosis

Additionally, the Department proposes to add the following three diseases which are not on the NNID list to ch. HFS 145 Appendix A:

1. Any illness caused by an agent that is foreign, exotic or unusual to Wisconsin, and that has public health implications. Section 250.02, Stats., authorizes the Department to take action to ascertain the presence of any communicable disease. This generic reporting requirement is in lieu of a long listing of individual exotic diseases that are rare but have major public ramifications. It also takes into account the possible emergence of important diseases that are as yet unknown. Each state adjacent to Wisconsin requires that unusual illnesses be reported.
2. Lymphocytic Choriomeningitis Virus (LCMV) infections. In 2003, LCMV was transmitted in organs from an infected Wisconsin donor to four organ recipients. Implementation of public health measures upon identification of a case could potentially limit further exposures.
3. Transmissible spongiform encephalopathy (TSE, human). Approximately 50% of states currently mandate reporting of human TSEs and the Division of Public Health already maintains surveillance for human TSEs. Mandatory reporting will simplify the process of obtaining clinical information, especially from out-of-state providers, and will permit the Department to describe more accurately the burden of endemic TSEs of humans.

Additionally, the Department proposes to delete eight diseases, none of which are on the NNID list, from ch. HFS 145 Appendix A. The Department does not anticipate that there will be any adverse impact on the public from deletion of the eight diseases from mandatory reporting:

1. Amebiasis
2. Cat scratch disease (infection caused by *Bartonella* species)
3. Encephalitis, viral (other than arboviral)
4. Genital herpes infection (first episode identified by health care provider)
5. Hepatitis non-A, non-B, (acute)
6. Meningitis, viral (other than arboviral)
7. Reye syndrome
8. Typhus fever

Additionally, the Department proposes to change the way the following five diseases are listed in ch. HFS 145 Appendix A:

1. Change Arboviral infection (encephalitis/meningitis) to Arboviral Disease. The proposed change in terminology makes reporting requirements consistent with current Wisconsin public health practice. This group of diseases is currently on the NNID list.

2. Change *E. coli* 0157:H7, and other enterohemorrhagic *E. coli*, enteropathogenic *E. coli*, enteroinvasive *E. coli*, enterotoxigenic *E. coli* to *E. coli* 0157:H7 and other Shiga toxin-producing *E. coli* (STEC), enteropathogenic *E. coli*, enteroinvasive *E. coli*, and enterotoxigenic *E. coli*. In 2005, CSTE recommended that the enterohemorrhagic *Escherichia coli* (EHEC) condition name be revised to Shiga toxin-producing *Escherichia coli* (STEC) to more accurately describe the condition under surveillance.
3. Change Hepatitis E from a category I disease to a category II disease because this disease does not occur often in the United States and person-to-person transmission is uncommon.
4. Change Suspected Outbreaks of Other Acute or Occupational-related diseases from category II to category I because a possible outbreak requires immediate attention.
5. Change Varicella (chickenpox) – report by number of cases only to Varicella (chickenpox). In 2003, CDC encouraged all states to establish individual case reporting systems to monitor the impact of the varicella vaccination program on varicella morbidity. This level of surveillance is now operationally feasible because the number of cases is far fewer than in the pre-vaccination era. Varicella is on the NNID list.

Lastly, the Department proposes to:

- 1) Alphabetize the diseases in ch. HFS 145 Appendix A to make the list easier for persons reporting communicable diseases to use.
- 2) Allow reports of communicable diseases to be submitted electronically. Electronic transmission of reports currently occurs and is expected to increase.
- 3) Cite the most recent editions of the *Sexually Transmitted Diseases Treatment Guidelines* and the *Control of Communicable Diseases Manual* to make the references current.
- 4) Require laboratories to forward specimens to the State Laboratory of Hygiene for confirmatory or investigation purposes if requested by the State Epidemiologist.
- 5) Require laboratories and health care facilities to report a negative test result on a case or a suspected case to justify release from isolation or quarantine if requested by the State Epidemiologist or Local Health Officer.
- 6) Remove language requiring a person, laboratory or health care facility to report the total number of cases of other communicable diseases listed in ch. HFS 145 Appendix A to the local health officer on a weekly basis because varicella, the only disease reported in this manner, will now be reported as individual cases.

The intended goals of the proposed rulemaking are to make communicable disease reporting requirements in Wisconsin current, consistent with CSTE recommendations and supportive of Wisconsin public health practice. Instead of regulatory action, medical providers, health care facilities and laboratories could be asked to submit reports voluntarily. However, such reporting would be incomplete and more staff time would be required to solicit the reports. Without this proposed rulemaking, disease reporters would continue to complete and submit reports of some communicable diseases unnecessarily, national communicable disease data would not reflect diseases occurring in Wisconsin, and the rule language would be outdated.

Members of the public who may be affected by the proposed rulemaking are those who acquire one of the communicable diseases the proposed rulemaking adds. Other members of the public who may be affected are the individual's family members or other contacts who were spared infection because public health measures were applied.

Summary of, and comparison with, existing or proposed federal regulations:

There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

Comparison with rules in adjacent states:

Illinois:

Illinois Administrative Code Title 77, Chapter 1, Subchapter K, Part 690, Section 690 requires reporting any unusual case or cluster of cases that may indicate a public health hazard (690.295), VISA/VRSA (690.661), and varicella (690.350). These rules became effective 6/30/03 and are currently being updated. The new rules will require reporting of influenza-associated pediatric death, SARS, TSE (as Creutzfeldt Jakob Disease) and vibriosis. These rules have been sent out for comment and are expected to take effect in the fall of 2007.

Iowa:

Iowa Administrative Code (IAC) 641-1.3 (139A) makes reportable a number of diseases and conditions, including any uncommon disease and vancomycin-resistant *Staphylococcus aureus*. IAC 641-1.1 (139A) includes SARS in the definition of quarantinable diseases. Quarantinable diseases are immediately reportable under 641-1.4 (1). Isolates of organisms from diseases on the list of reportable diseases or conditions marked with a "~" must be sent to the University of Iowa Hygienic Laboratory. IAC 641-1.4 (3) requires the reporting agency to provide test results necessary to the investigation, including positive, pending and negative test results. These rules became effective 3/10/04.

Michigan:

Michigan Administrative Code 325.172 makes reportable a number of diseases and conditions, including the unusual occurrence, outbreak or epidemic of any condition (bbbb), laboratory-confirmed poliovirus infection (vv), SARS (jjj), TSE [as spongiform encephalopathy (lll)], VISA/VRSA (mmm), and chickenpox (l). These rules became effective 9/23/05.

Minnesota:

Minnesota Chapter 4605.7040 makes reportable cases, suspected cases, carriers and deaths due to a number of diseases including influenza (26), SARS (15), TSE (52, VISA/VRSA (46), *Vibrio* species (58), and chickenpox [56 (a)]. Ch. 4605.7050 requires reporting of any unusual case incidence. Ch. 4605.7030 Subpart 3 B requires laboratories to forward to the Minnesota Department of Health Public Health Laboratory all clinical materials specified in the chapter or upon the request of the commissioner. These rules became effective 9/13/05.

The tables below compare the important elements in the Department's proposed rulemaking with current and proposed communicable disease reporting rules in Illinois, Iowa, Michigan and Minnesota.

State	Any unusual illness	Influenza-associated pediatric death	LCMV	Poliovirus, nonparalytic	SARS-CoV	TSE	VISA & VRSA	Vibriosis
Illinois	Yes	No, but soon	No	No	No, but soon	No, but soon	Yes - Both	No, but soon
Iowa	Yes	No	No	No	Yes	No	Yes - VRSA	No
Michigan	Yes	No	No	Yes	Yes	Yes	Yes - Both	No
Minnesota	Yes	Yes	No	No	Yes	Yes	Yes - Both	Yes

State	Individual Varicella Case Reports	Laboratory must forward specimen upon request	Laboratory must report negative test result upon request
Illinois	Yes	Yes	No
Iowa	No	Yes	Yes
Michigan	Yes	No	No
Minnesota	Yes	Yes	No

Summary: All of Wisconsin's neighboring states require the reporting of illnesses caused by unusual agents. The reporting requirements this rulemaking proposes are most similar to those in Minnesota, the state with the most recently enacted reporting requirements. The reporting requirements in Illinois will also closely resemble those Wisconsin proposes when its proposed rules take effect later in 2007. However, none of Wisconsin's neighboring states require that LCMV be specifically reported. LCMV cases in those states would still be reported under the requirement that illnesses caused by unusual agents be reported.

Summary of factual data and analytical methodologies:

This rule was amended in consultation with Bureau of Communicable Diseases and Preparedness Communicable Disease Epidemiology Section staff. Wisconsin's list of reportable diseases in ch. 145 Appendix A was reviewed and compared to the CSTE NNID list in the 2007 Summary of Changes to the Nationally Notifiable Diseases Surveillance System that the Centers for Disease Control and Prevention sent to State and Territorial Epidemiologists on December 5, 2006. Additionally, the communicable disease reporting requirements in states adjacent to Wisconsin were identified and described. A draft of the amended rule was circulated to and revised in response to comments from the following groups: the Wisconsin Association of Local Health Departments and Boards; Local Health Officers; the State Laboratory of Hygiene and its Laboratory Reporting Network; the Association for Professionals in Infection Control; the Wisconsin Council on Immunization Practices and the Surveillance Epidemiology Workgroup.

Analysis and supporting documents used to determine effect on small business:

Chapter HFS 145 requires medical providers, health care facilities and laboratories to report communicable diseases listed in Appendix A to the Local Health Officer or the State Epidemiologist. This rulemaking proposes adding 9 diseases to, and subtracting 8 diseases from, ch. HFS 145 Appendix A. The rulemaking includes no fees and failure to comply with the

rulemaking carries no penalties. Costs to the private sector include completing and mailing communicable disease case report forms, or keying-in and transmitting data electronically, to local health departments or the Department. Communicable disease reporting is frequently performed by the infection control practitioner or clerical staff.

This rulemaking is unlikely to have a significant economic impact on the private sector generally, and small businesses in particular, for the following reasons:

- Communicable disease reporting requirements and reporting mechanisms have been in place for many years.
- Additions of reportable diseases to ch. HFS 145 Appendix A have been balanced by deletions from it. Some of the deleted diseases which occur relatively frequently, e.g., genital herpes and cat scratch fever, will no longer be reported.
- Most of the diseases being added to the list, although serious in nature and of public health importance, occur so rarely that few if any cases are expected annually.
- Since the largest laboratories performing testing will be reporting automatically through electronic laboratory reporting, there will be minimal impact on these laboratories.

Effect on small business:

Pursuant to the foregoing analysis, the Department believes that these rules will not have a significant economic impact on the health care facilities or laboratories that meet the definition of small businesses.

Agency contact person:

Marjorie Hurie, RN, MS
Bureau of Communicable Diseases
PO Box 2659
Madison, WI 53701
608-264-9892

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at <http://adminrules.wisconsin.gov> after the hearing is scheduled.

TEXT OF PROPOSED RULE

Section 1: HFS 145.03 (19) and Note, and (20) are amended to read:

HFS 145.03 (19) "Other disease or condition having the potential to affect the health of other persons" means a disease that can be transmitted from one person to another but that is not listed in Appendix A of this chapter and therefore is not reportable under this chapter, although it is listed in *Control of Communicable Diseases Manual*, ~~16th edition (1995)~~ 18th edition (2004), edited by ~~Abram S. Benenson~~ David L. Heymann, and published by the American Public Health Association, unless specified otherwise by the state epidemiologist.

Note: The handbook, *Control of Communicable Diseases Manual*, ~~16th edition (1995)~~ 18th edition (2004), edited by ~~Abram S. Benenson~~ David L. Heymann, is on file in the Department's Division of Public Health, the ~~Revisor of Statutes~~ Legislative Reference Bureau (LRB), and is available for purchase from the American Public Health Association, ~~1015 Fifteenth St., NW, Washington, D.C., 20005~~ Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

(20) "Outbreak" means ~~the occurrence of communicable disease cases, in a particular geographical area of the state, in excess of the expected number of cases~~ an unusual aggregation of health events that are grouped together in a short time period and limited geographic area.

Section 2. HFS 145.04 (1) (bg), (br) and (cm) are created to read:

HFS 145.04 (1) (bg) Each laboratory shall forward a specimen to the state laboratory of hygiene, or another laboratory designated by the state epidemiologist, for confirmatory or investigation purposes if requested by the state epidemiologist.

(br) Each laboratory shall report a negative test result to the local health officer to justify release from isolation or quarantine if requested by the state epidemiologist or the local health officer.

(cm) Each health care facility shall report a negative test result to the local health officer to justify release from isolation or quarantine if requested by the state epidemiologist or the local health officer.

Section 3. HFS 145.04 (2) (b) is amended to read:

HFS 145.04 (2) (b) Reports may be written, ~~or verbal,~~ or by electronic transmission. Written reports shall be on the individual case report form provided by the department and distributed by the local health officer or on a form containing the information required under par. (a). Reports shall be submitted to the local health officer or, if required under Appendix A of this chapter, to the state epidemiologist.

Section 4. HFS 145.04 (3) (c) is repealed.

Section 5. HFS 145.05 (2), (3) and (4) Note are amended to read:

HFS 145.05 (2) Local health officers shall follow the methods of control set out in section 9 under each communicable disease listed in the ~~17th~~ 18th edition (2004) of *Control of Communicable Diseases Manual*, edited by ~~James Chin~~ David L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist. Specific medical treatment shall be prescribed by a physician or an advanced practice nurse prescriber.

(3) Any person licensed under ch. 441 or 448, Stats., attending a person with a communicable disease shall instruct the person in the applicable methods of control contained in *Control of Communicable Diseases Manual*, 17th18th edition (~~2000~~2004), edited by James ChinDavid L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist, and shall cooperate with the local health officer and the department in their investigation and control procedures-

(4) Note: The handbook, *Control of Communicable Diseases Manual*, 17th18th edition 2000(2004), edited by James ChinDavid L. Heymann, is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau, and is available for purchase from the American Public Health Association, ~~1015 Fifteenth St., NW, Washington, DC 20005~~Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

Section 6. HFS 145.10 (1) and Note are amended to read:

HFS 145.10 Restriction and management of patients and contacts. (1) All persons with infectious tuberculosis or suspected tuberculosis, and their contacts, shall exercise all reasonable precautions to prevent the infection of others, under the methods of control set out in section 9 under tuberculosis, pages ~~525565~~ to ~~530572~~, listed in the 17th18th edition (~~2000~~2004) of *Control of Communicable Diseases Manual*, edited by James ChinDavid L. Heymann, published by the American Public Health Association, unless specified otherwise by the state epidemiologist.

Note: The handbook *Control of Communicable Diseases Manual*, 17th18th edition (~~2000~~2004), edited by James ChinDavid L. Heymann, is on file in the Revisor of Statutes Bureau and the Secretary of State's Office, and is available for purchase from the American Public Health Association, ~~800 I Street, NW, Washington, DC 20001-3710~~Publications Sales, PO Box 933019, Atlanta, GA 31193-3019.

Section 7. HFS 145.22 and Note are amended to read:

HFS 145.22 Treatment guidelines. Nationally recognized guidelines, including the "~~1998 Guidelines for Treatment of Sexually Transmitted Diseases~~""Sexually Transmitted Diseases Treatment Guidelines, 2006" published by the U.S. Department of Health and Human Services, shall be considered in the treatment of sexually transmitted diseases unless otherwise specified by the state epidemiologist. Specific medical treatment shall be prescribed by a physician or advanced practice nurse prescriber.

Note: The publication, "~~1998 Guidelines for Treatment of Sexually Transmitted Diseases~~""Sexually Transmitted Diseases Treatment Guidelines, 2006," is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State's Office, and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402-9325. Telephone: (202) 512-1800.

Section 8. HFS 145 APPENDIX A is repealed and recreated to read:

CHAPTER HFS 145

APPENDIX A COMMUNICABLE DISEASES AND OTHER NOTIFIABLE CONDITIONS

CATEGORY I:

The following diseases are of urgent public health importance and shall be reported IMMEDIATELY by telephone or fax to the patient's local health officer upon identification of a case or suspected case. In addition to the immediate report, complete and mail an Acute and Communicable Diseases Case Report (DOH 4151) to the address on the form, or enter the data into the Wisconsin Electronic Disease Surveillance System, within 24 hours. Public health intervention is expected as indicated. See s. HFS 145.04 (3) (a).

Any illness caused by an agent that is foreign, exotic or unusual to Wisconsin, and that has public health implications⁴

Anthrax^{1,4,5}

Botulism^{1,4}

Botulism, infant^{1,2,4}

Cholera^{1,3,4}

Diphtheria^{1,3,4,5}

Haemophilus influenzae invasive disease, (including epiglottitis)^{1,2,3,5}

Hantavirus infection^{1,2,4,5}

Hepatitis A^{1,2,3,4,5}

Measles^{1,2,3,4,5}

Meningococcal disease^{1,2,3,4,5}

Outbreaks, foodborne or waterborne^{1,2,3,4}

Outbreaks, suspected, of other acute or occupationally-related diseases

Pertussis (whooping cough)^{1,2,3,4,5}

Plague^{1,4,5}

Poliovirus infection (paralytic or nonparalytic)^{1,4,5}

Rabies (human)^{1,4,5}

Ricin toxin^{4,5}

Rubella^{1,2,4,5}

Rubella (congenital syndrome)^{1,2,5}

Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)^{1,2,3,4}

Smallpox^{4,5}

Tuberculosis^{1,2,3,4,5}

Vancomycin-intermediate Staphylococcus aureus (VISA) and Vancomycin-resistant Staphylococcus aureus (VRSA) infection^{1,4,5}

Yellow fever^{1,4}

CATEGORY II:

The following diseases shall be reported to the local health officer on an Acute and Communicable Disease Case Report (DOH 4151) or by other means or by entering the data into the Wisconsin Electronic Disease Surveillance System within 72 hours of the identification of a case or suspected case. See s. HFS 145.04 (3) (b).

Arboviral disease^{1,2,4}

Babesiosis^{4,5}

Blastomycosis⁵

Brucellosis^{1,4}

Campylobacteriosis (campylobacter infection)^{3,4}

Chancroid^{1,2}

Chlamydia trachomatis infection^{2,4,5}

Cryptosporidiosis^{1,2,3,4}

Cyclosporiasis^{1,4,5}

Ehrlichiosis (anaplasmosis)^{1,5}

E. coli 0157:H7, other Shiga toxin-producing E. coli (STEC), enteropathogenic E. coli, enteroinvasive E. coli, and enterotoxigenic E.

Meningitis, bacterial (other than Haemophilus influenzae, meningococcal or streptococcal, which are reportable as distinct diseases)²

Mumps^{1,2,4,5}

Mycobacterial disease (nontuberculous)

Psittacosis^{1,2,4}

Pelvic inflammatory disease²

Q Fever^{4,5}

Rheumatic fever (newly diagnosed and meeting the Jones criteria)⁵

Rocky Mountain spotted fever^{1,2,4,5}

Salmonellosis^{1,3,4}

Syphilis^{1,2,4,5}

coli.^{1,2,3,4}
 Giardiasis^{3,4}
 Gonorrhea^{1,2,4,5}
 Hemolytic uremic syndrome^{1,2,4}
 Hepatitis B^{1,2,3,4,5}
 Hepatitis C^{1,2}
 Hepatitis D^{2,3,4,5}
 Hepatitis E^{3,4}
 Histoplasmosis⁵
 Influenza-associated pediatric death¹
 Influenza A virus infection, novel subtypes
 Kawasaki disease²
 Legionellosis^{1,2,4}
 Leprosy (Hansen Disease)^{1,2,3,4,5}
 Leptospirosis⁴
 Listeriosis^{2,4}
 Lyme disease^{1,2}
 Lymphocytic Choriomeningitis Virus (LCMV)
 infection⁴
 Malaria^{1,2,4}

Shigellosis^{1,3,4}
 Streptococcal disease (all invasive disease
 caused by Groups A and B Streptococci)
 Streptococcus pneumoniae invasive disease
 (invasive pneumococcal)¹
 Tetanus^{1,2,5}
 Toxic shock syndrome^{1,2}
 Toxic substance related diseases:
 Infant methemoglobinemia
 Lead intoxication (specify Pb levels)
 Other metal and pesticide poisonings
 Toxoplasmosis
 Transmissible spongiform encephalopathy
 (TSE, human)
 Trichinosis^{1,2,4}
 Tularemia⁴
 Typhoid fever^{1,2,3,4}
 Varicella (chickenpox)^{1,3,5}
 Vibriosis^{1,3,4}
 Yersiniosis^{3,4}

CATEGORY III:

The following diseases shall be reported to the state epidemiologist on an AIDS Case Report (DOH 4264) or a Wisconsin Human Immunodeficiency Virus (HIV) Infection Confidential Case Report (DOH 4338) or by other means within 72 hours after identification of a case or suspected case. See s. 252.15 (7) (b), Stats., and s. HFS 145.04 (3) (b).

Acquired Immune Deficiency Syndrome (AIDS)^{1,2,4}
 Human immunodeficiency virus (HIV) infection^{2,4}
 CD4 + T-lymphocyte count < 200/mL, or CD4 + T-lymphocyte percentage of total lymphocytes of < 14²

Key:

¹Infectious diseases designated as notifiable at the national level.

²Wisconsin or CDC follow-up form is required. Local health departments have templates of these forms in the Epinet manual.

³High-risk assessment by local health department is needed to determine if patient or member of patient's household is employed in food handling, day care or health care.

⁴Source investigation by local health department is needed.

⁵Immediate treatment is recommended, i.e., antibiotic or biologic for the patient or contact or both.

EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health and Family Services

Dated:

Kevin R. Hayden, Department Secretary

SEAL:



ADMINISTRATIVE RULES – FISCAL ESTIMATE

1. Fiscal Estimate Version

Original Updated Corrected

2. Administrative Rule Chapter Title and Number

HFS 145, Control of Communicable Diseases

3. Subject

To revise ch. HFS 145, relating to communicable disease reporting and follow-up.

4. State Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Existing Revenues

Decrease Existing Revenues

Increase Costs

Yes No

May be possible to absorb within agency's budget.

Decrease Costs

5. Fund Sources Affected:

GPR FED PRO PRS SEG SEG-S

6. Affected Ch. 20, Stats. Appropriations:

7. Local Government Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Increase Costs

Decrease Costs

8. Local Government Units Affected:

Towns Villages Cities Counties School Districts WTCS Districts Others:

9. Private Sector Fiscal Effect (small businesses only):

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Yes No May have significant economic impact on a substantial number of small businesses

Increase Costs

Yes No

May have significant economic impact on a substantial number of small businesses

Decrease Costs

10. Types of Small Businesses Affected:

Medical providers, health care facilities and laboratories

11. Fiscal Analysis Summary

These are updating amendments to the Department's rules for reporting communicable diseases and taking action to control their spread.

The rulemaking order adds 9 diseases to, deletes 8 diseases from, and changes the way 5 diseases appear on the list of reportable communicable diseases in Appendix A of the rules. The Department is authorized by s. 990.01 (5g), Stats., to add diseases to that list by rule. The rulemaking order also updates references, deletes outdated language, requires laboratories to forward specimens to a public health laboratory for additional testing if requested by the State Epidemiologist and requires laboratories and health care facilities to report negative test results to the local health officer if requested by the State Epidemiologist or the local health officer.


Anticipated costs to the Department include layout and printing costs associated with revising and reprinting the Division of Public Health's Communicable Disease Case Report form (DPH 4151); staff time to inform the mandated reporting agencies of the rule revisions through educational forums, e.g., Communicable Disease Spring Seminars, and scheduled meetings, e.g., regional Association of Practitioners of Infection Control chapter meetings and the State Laboratory of Hygiene's Laboratory Reporting Network; and staff time to prepare notices of the rule revisions for publication in the Wisconsin State Medical Journal, on the Department's web site and the Health Alert Network. These costs are insignificant and will be absorbed within the Bureau of Communicable Diseases and Preparedness budget and staff responsibilities.

The rule changes will not affect the expenditures or revenues of Local Health Departments. Local Health Officers are responsible under s. 252.03 (1), Stats., for investigating, preventing and controlling communicable diseases. Most of the diseases being added to Appendix A have been balanced by deletions from it and, with the exception of varicella (chickenpox), occur so rarely that few if any cases are expected annually. The addition of varicella reporting by individual case report to Appendix A (summary data on approximately 1,000 cases were reported in 2006) has been more than balanced by the deletion of genital herpes (more than 3,000 cases were reported in 2005).

This rulemaking is unlikely to have a significant economic impact on the private sector generally, and any health care facilities or laboratories that may meet the definition of small business in 227.114 (1), Stats., in particular. It includes no fees, failure to comply with the rulemaking carries no penalties and communicable disease reporting mechanisms are already in place. Usual costs to the private sector include completing and mailing communicable disease case reports forms, or keying-in and transmitting data electronically, to local health departments or the Department. These tasks are frequently performed by the infection control practitioner or clerical staff. Since the largest laboratories will be reporting automatically through electronic laboratory reporting, there will be minimal impact on these laboratories. Requests from the State Epidemiologist or the Local Health Officer for negative test results to justify release from isolation or quarantine are anticipated to be infrequent, as are requests from the State Epidemiologist that specimens to be forwarded to a public health laboratory for confirmatory or investigation purposes.

12. Long-Range Fiscal Implications

None known.

13. Name - Prepared by Marjorie Hurie	Telephone Number 608-264-9892	Date 7/18/07
14. Name - OSF Analyst Reviewer Ellen Hadidian	Telephone Number 608-266-8155	Date 9/28/07
Signature - DHFS Secretary or Designee 	Telephone Number 266-4450	Date 10-5-07